Department of Health and Human Services
Substance Abuse and Mental Health Services Administration
Center for Substance Abuse Prevention
Division of Workplace Programs

National Laboratory Certification Program (NLCP) **Program Document #39**

Date: March 28, 2001

Subject: Revised Inspection and PT Programs and New Fee Schedule

This notice describes changes in the NLCP and the new fees needed to fully support these changes.

We are changing the number of inspectors that are used for some of the laboratory inspection categories. The consolidation and growth of several laboratories has caused a significant increase in their workloads. These increases have made it difficult for inspectors to review a sufficient number of non-negative (i.e., positive, adulterated, and substituted) test results in the time allotted. By increasing the number of inspectors, the percentage of non-negative test results reviewed by the inspection teams will be comparable between the different categories. The inspection configurations for Categories I and II remain unchanged. That is, a Category I inspection uses 2 inspectors doing a 2-day inspection, and a Category II inspection uses 3 inspectors doing a 2-day inspection. A Category III inspection requires a team of 4 inspectors (rather than the current 3 inspectors) conducting a 3-day inspection. A Category IV inspection requires a team of 5 inspectors (rather than the current 4 inspectors) conducting a 3-day inspection. Finally, a new Category V inspection has been established for the laboratories that have extremely large workloads. A Category V inspection will have a team of 6 inspectors conducting a 3-day inspection. The category in which each laboratory is assigned is determined by its daily regulated specimen workload, the number of accessioning staff, and the number of certifying scientists. Each laboratory's category is reevaluated at least annually to ensure that it is in the appropriate inspection category.

We are changing the duties of some of the inspectors, that is, each inspector on a team will not conduct a complete checklist inspection. For Categories I and II, one inspector will conduct a complete checklist inspection. For Categories III, IV, and V, two inspectors will conduct a complete checklist inspection. In each category, the remaining inspector(s) will focus their efforts on a review of the non-negative (i.e., positive, adulterated, substituted, and unsuitable) primary specimen and split specimen test results reported by a laboratory during the 6-month period prior to the inspection. Although each inspector is not completing a checklist, the inspection is still a team inspection and all team members will tour the laboratory and participate in documenting/verifying any checklist deficiencies.

We are also requiring each laboratory to submit a list of the non-negative primary specimens and split specimens reported for a 6-month period prior to an inspection to the NLCP contractor.

Specific guidance on the format and information to be included on the list will be provided by the NLCP contractor. The NLCP contractor will review the list and direct the laboratory to make available all the batch data and documentation for a selected number of those non-negative and split specimen test results to facilitate review by the inspectors during the inspection.

Under the special inspection category, for those laboratories that use corporate laboratory information management systems (LIMS) not under the direct day-to-day observation and control of the laboratory responsible person (RP) that it serves, there will be a special annual inspection of the LIMS and the facility where the LIMS is located. This special inspection will be a 2-day inspection using 2 inspectors. Each corporate LIMS facility will undergo one annual inspection regardless of the number of separate laboratories that it serves.

The set of quarterly performance testing (PT) samples is being increased from 15 to 20 samples to ensure that the laboratory's specimen validity testing procedures are properly challenged and evaluated. The initial set of PT samples is also being increased for this same reason.

The new fee schedule is as follows:

	Fee ($)	# Inspectors	# Days
Application	1,000		
Inspections			
Initial	8,800	2	2
Maintenance			
Category I	8,800	2	2
Category II	12,000	3	2
Category III	18,500	4	3
Category IV	23,000	5	3
Category V	27,500	6	3
Special	Actual Cost		
Performance Testing			
Initial Set	1,600		
Maintenance Set	1,600		
Remedial Action	1,200		
Lab Withdrawal (Final Audit Inspection)	2,000 - 6,000		

This new fee schedule is effective **July 1, 2001**. It will be evaluated periodically to ensure that the fees accurately reflect the costs associated with each activity.

If you have any questions about the changes, please contact my staff at (301) 443-6014 or by email: wvogl@samhsa.gov

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Director
Division of Workplace Programs